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Date: August 5, 2009 Name: Heidi A. Dare, Reg. No. 50, 775. Signature: Heidi A. Dare

Attorney Docket No. 8465/40

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Lasse W. Mogensen, et al.	:	
Serial No.:	10/687,568	:	Confirmation No.: 7139
Filed:	October 15, 2003	:	Group Art Unit: 3767
For:	INJECTOR DEVICE FOR PLACING A SUBCUTANEOUS INFUSION SET	:	Examiner: Elizabeth Moulton

APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Appeal Brief is in response to the Final Office Action mailed April 22, 2009[1].

[1] Appellants filed a Notice of Appeal on August 26, 2008 and an Appeal Brief on November 26, 2008. A Final Office Action was mailed on April 22, 2009. A second Notice of Appeal was filed on June 5, 2009. Appellants' transmittal filed with the second Notice of Appeal authorized charging the deposit account of the undersigned's firm in case additional fees were required and so the $30 due for the second Notice of Appeal is believed to have been paid ($510 was previously paid for the Notice of Appeal filed on August 26, 2008). Since the present Appeal Brief is being filed within two months of the date of receipt of the second Notice of Appeal, the present Appeal Brief is timely filed.

I. REAL PARTY IN INTEREST

Unomedical A/S, a ConvaTec Company, which is owned by Nordic Capital and Avista Capital Partners, is the real party of interest in this Appeal.

II. RELATED APPEALS AND INTERFERENCES

The undersigned, Heidi A. Dare, is aware of two appeals filed with the Board of Patent Appeals and Interferences that may be related to, would directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal. One appeal is pending and regards United States Patent Application Serial No. 10/813,214 ("the '214 application"). A Notice of Appeal was filed on June 3, 2009 regarding the '214 application. The '214 application is a continuation-in-part of the present application.

A second appeal is also pending that regards United States Patent Application Serial No. 11/031,635 ("the '635 application"), which is a continuation of the '568 application. A Notice of Appeal was filed on October 3, 2008 regarding the '635 application. The latest document filed was a Reply on June 16, 2009.

The undersigned is unaware of any other prior or pending appeal, interference, or judicial proceedings that may be related to, directly affect or be affected by, or have a bearing on the Board's decision in this Appeal.

III. STATUS OF CLAIMS

Claims 55-64, 66 and 69-73, all claims presented, are rejected and appealed. Claims 1-39 and 44-49 are canceled. Claims 40-43, 50-54, 65, 67 and 68 are allowed. No claims are objected to or withdrawn from consideration.

IV. STATUS OF AMENDMENTS

Prior to the filing of the present Brief on Appeal to the Board of Patent Appeals and Interferences, an Amendment was filed on December 21, 2006 in response to a Final Office Action mailed on August 1, 2006. The Amendment was entered since it was filed concurrently with a Request for Continued Examination.

An Amendment was filed on October 31, 2007 in response to a Final Office Action mailed on July 2, 2007. The Amendment was entered since it was filed concurrently with a Request for Continued Examination. A Supplemental Amendment was filed on December 10, 2007 which was considered.

No amendments were filed in response to the Final Office Action mailed on May 23, 2008. An Appeal Brief was filed November 26, 2008. In response to the Appeal Brief, the Examiner issued another Final Office Action on April 6, 2009 in which the grounds for reopening prosecution are unclear to Appellants as the same art was cited. A Supplemental Final Office Action was mailed on April 22, 2009 at Appellant's request to clarify procedurally the actions taken by the Examiner. The Examiner issued the

Final Office Action mailed April 22, 2009 after the filing of the Appeal Brief to clarify the issues for appeal. Appellants expect that no additional Office Action will follow this Appeal Brief.

V. SUMMARY OF CLAIMED SUBJECT MATTER

1. Summary of Embodiments of Invention

An understanding of the invention of independent claims 55, 56, 58, 61 and 66 can be made upon a review of the embodiments of the invention shown in FIGS. 1-12, 17-21e, 23a and 23b of the specification. Note that in the description to follow, like elements will employ identical identification numerals.

In accordance with the invention, FIGS. 1-5 show an injector device 10 that has an infusion set 14 with a cannula 26 extending therefrom (Page 6, lines 29-32). The injector device 10 includes a plunger 30 having thereon a medical insertion needle 12 with a pointed end 12A (Page 7, lines 1-2). The plunger 30 is arranged for longitudinal sliding movement within a device housing 28 between a forward advanced position (FIGS. 3 and 4) and a rearward retracted position (FIG. 1 and 2) (Page 7, lines 2-5). The device housing and the plunger 30 can be formed in a molding process (Page 7, lines 6-7).

The infusion set 14 is used to infuse medical fluids to a patient, and generally includes a housing with an internal chamber (not shown) that receives medication via infusion tubing (Page 7, lines 9-11). As shown in FIG. 1, a base 24 of the infusion set 14 is provided on the housing for stable affixation thereof to the skin of the patient (Page

7, lines 11-13). The base 24 may carry an adhesive and be provided with a release sheet 14' (FIG. 2) which is removed to expose the adhesive prior to placement of the infusion set (Page 7, lines 13-15). As shown in FIG. 1, the infusion set has a protruding soft and flexible cannula 26, which communicates with the internal chamber, and a passage sealed by a sealing membrane extends through the housing opposite the cannula 26 (Page 7, lines 16-19). As shown in FIGS. 1-2, the medical insertion needle 12 of the injector device 10 extends through the passage, into the internal chamber and through the cannula 26, when the infusion set 14 is mounted in position on the injector device (Page 7, lines 19-22). After transcutaneous placement of the cannula 26, the injector device 10 with the insertion needle 12 is retracted from the infusion set 14 to permit medication delivery through the cannula 26 to the patient (Page 7, lines 22-25).

The injector device 10 includes a trigger-type actuator mechanism for transcutaneous placement of the insertion needle 12 which is secured to the plunger 30, with the insertion needle 12 oriented at an angular position relative to the skin of the patient (Page 8, lines 11-14).

As shown in FIG. 3, the plunger 30 has a recessed head 32 at a lower or forward end thereof shaped for receiving the housing of the subcutaneous infusion set 14 (Page 8, lines 18-19). Centrally in the recess, the head 32 is provided with the metal insertion needle 12, which is securely connected thereto (Page 8, lines 20-21). As shown in FIG. 2, a rear end of the plunger 30 has a trigger-type actuator assembly 34 cooperating with the rear end of the device housing 28, and includes a stem, which is longitudinally split

to define a pair of trigger arms 38 which have outturned trigger fingers 58 on the sides thereof (Page 8, lines 28-32). As shown in FIGS. 1-2, the trigger actuator assembly 34 is adapted to hold the plunger 30 in a retracted position, against the force of a compressed helical drive spring 36 (Page 8, lines 32-34). The trigger arms 38 of the actuator assembly 34 are adapted for fingertip depression to release the plunger 30 for spring-loaded travel toward the advanced position, and for corresponding transcutaneous placement of the insertion needle 12, and of the cannula 26 travelling therewith, through the patient's skin (Page 8, line 34-page 9, line 4). In an alterative embodiment, release of the plunger 30 may be caused by pressing manually on diametrically opposed outside areas of the device housing 28 to deform the housing 28 and thereby effect release of the trigger arms 38 (Page 9, lines 4-7).

As shown in FIGS. 1-5, a hollow bore of the device housing 28 has a size and shape for reception of the infusion set 14, with the insertion needle 12 extending through the cannula 26 and extending together with the cannula 26 in a direction for placement on a patient (Page 9, lines 13-16). A releasable cover sheet 42 (FIGS. 1 and 2) is preferably secured to the device housing 28 at the nose end thereof to indicate the sterility of the infusion set 14 (Page 9, lines 16-18).

As shown in FIGS. 1-2, the trigger assembly 34 is initially locked against a shoulder 66 formed on the device housing 28 by the trigger fingers 58 (Page 10, lines 5-7). As shown in FIGS. 1-2, the drive spring 36 includes a coil spring positioned about the stem on the plunger 30 and reacts between a rearward face 64 of the plunger head

32, and an internal shoulder 66' on the device housing 28 (Page 10, lines 7-10). The drive spring 36 normally biases the plunger 30 toward the advanced position (Page 10, lines 10-11). In a retracted plunger position shown in FIG. 1, the drive spring 36 is retained in a compressed and cocked condition, with the cannula 26 of the infusion set 14 being received on the insertion needle 12 (Page 10, lines 14-16). The releasable cover sheet 42 is then applied to the device housing 28 at the nose end thereof (Page 10, lines 16-18).

In use of the injector device 10 with the infusion set 14, the cover sheet 42 is first removed and the injector device 10 is placed firmly against the patient's skin, with the infusion set 14 supported in the proper orientation and at a predetermined distance from the skin (Page 10, lines 20-23). A cap 94 shown in FIGS. 1-2, which prevents accidental projection of the infusion set 14 by preventing access to the trigger arms 38, is removed (Page 10, lines 23-25). Simple depression of the arms 38 releases the cocked plunger 30 for spring-loaded travel rapidly albeit with a controlled speed and force of insertion, to ensure penetration of the patient's skin with minimal discomfort, and in a manner which properly places the insertion needle and cannula 26 (Page 10, lines 25-28).

Following placement of the infusion set 14 the injector device with insertion needle 12 is withdrawn quickly and easily from the cannula (Page 10, lines 30-31). Thereafter, the injector device can be discarded and the infusion set 14 can be used in a normal manner to deliver a selected medication through the infusion tubing and

cannula 26 to the patient (Page 10, lines 31-34). As shown in FIG. 4, the safety cap 94 may conveniently be adapted to cooperate with an annular recess 33 formed in the head 32 of the plunger 30 for providing protection against the needle 12 (Page 10, line 34–page 11, line 2).

The removable cap 94 and cover sheet 42 allow the injector device 10 and the infusion set 14 mounted on the insertion needle 12 to be sterilized using a sterilizing gas that flows through the membrane formed by the cover sheet 42 (Page 11, lines 4-9).

An alternative embodiment of the invention is shown schematically in FIGS. 6-12 wherein an injector device assembly including a modified injector device 110 includes a generally cylindrical hollow device housing 128, a plunger 130 and a trigger-type actuator 134 formed integrally with the plunger 130 (Page 11, lines 23-26). As shown in FIG. 6, cover 194 covers the top of the injector device 110 and a further cover 142 covers the bottom end of the injector device 110 (Page 11, lines 26-28).

As shown in FIGS. 6-11, the plunger 130 has a generally cylindrical form with a head 132 and a central pin 129 including a metal insertion needle 112 secured thereto in a molding process (Page 11, lines 30-33). The pin 129 stops at a distance from a pair of outwardly turned legs 138' at the head 132, to accommodate the infusion set 114 in the head 132 of the plunger 130 (Page 11, line 33-page 12, line 2). As shown in FIGS. 6-10, the insertion needle 112 extends through the infusion set 114 in a similar manner as described with reference to FIGS. 1-6 (Page 12, lines 2-3). As shown in FIGS. 6-7, an infusion set tubing 113 connected to the infusion set 114 is wound up in

the lower part of an annular space 115 between the device housing 128 and the plunger 130 (Page 12, lines 3-7).

As shown in FIG. 9, the device housing 128 again has a forward or nose end defining a flat and generally planar surface 125 (Page 12, lines 9-11). As shown in FIG. 6, the plunger 130 additionally includes a pair of resilient trigger arms 138 which are connected with the pair of outwardly turned legs 138' and which have out turned trigger fingers 158 at the sides thereof (Page 12, lines 11-13). The trigger arms 138 are adapted and sized for partial radial compression toward each other as they ride within the device housing when the plunger 130 is displaced from the advanced position (FIG. 6) to the retracted position (FIG. 9) (Page 12, lines 13-16). As the retracted position is reached, the trigger arms 138 are spring loaded by the resiliency to move first inwardly and then outwardly whereby the trigger fingers engage the upper surface of a shoulder 166 of the device housing 128 (Page 12, lines 17-20). In this position the trigger fingers 158 retain the plunger 130 in the retracted position (Page 12, lines 20-21).

As shown in FIGS. 6-7 and 12, a drive spring 136 is mounted within the device housing 128 to drive the plunger towards the nose of the device housing in the retracted position of the plunger 130, upon release of the trigger arms 138 (Page 12, lines 23-25).

Operation of the injector device assembly shown in FIGS. 6-12 is as follows. Since the injector device is preferably delivered to the patient in an uncocked state the plunger 130 must first be moved to the retracted position (Page 13, lines 11-14). To allow for retraction of the plunger 130, the upper cover 194, which spans across the

device housing 128, and the lower cover 142 are first removed, as shown in FIG. 7 (Page 13, lines 14-16). In this process, the infusion set 114 is exposed with the pointed end 112A of the insertion needle 112 projecting from the end of the soft flexible cannula 126 (Page 13, lines 17-19). The injector device 110 is then cocked by displacing the plunger 130 with respect to the device housing 128 as illustrated by the arrow in FIG. 9, until the fingers 158 engage the upper shoulder 166 of the device housing 120, indicating that the injector device is now ready for use (Page 13, lines 23-27). A release sheet 114' (FIG. 6) is then removed exposing an adhesive material on the bottom side of the infusion housing 114, and the patient or the nursing personnel then places the injector device on the patient's skin (Page 13, lines 27-30). The plunger 130 is released by application of an inwardly directed manual force on the arms 138 to transcutaneously place the insertion needle 112 and the cannula 126 (Page 13, lines 30-32). In an alternative embodiment, release of the plunger 130 may be caused by pressing manually on diametrically opposed outside areas of the device housing 128 to deform the housing 128 and thereby effect release of the trigger arms 138 (Page 13, line 32-page 14, line 2).

The injector device 110 is then removed, leaving the infusion set 114 on the patient's skin, illustrated by reference numeral 116, and the bottom cover 142 is then repositioned at the original place shown in FIG. 11 for protection of the insertion needle 112 which projects partially from the nose end of the device housing 128 (Page 14, lines 4-8).

The removable upper cover 194 and the bottom cover 142, when sealed to the device housing 128, allow the injector device 110 together with the infusion set 14 mounted on the insertion needle 112 to be sterilized in a conventional sterilization process, wherein one or both covers 142, 194 may include a permeable membrane allowing through-flow of the sterilizing agent (Page 14, lines 10-15).

FIGS. 13-16 show a third embodiment of the invention that includes an injector device 210 particularly suitable for the placement of a subcutaneous infusion set 214 at an acute angle relative to the skin of a patient (Page 14, lines 23-30). As best seen in FIG. 13, the injector device 210 has a device housing 228 with a flattened box-like structure (Page 14, lines 32-34). As shown in FIGS. 14-16, the injector device 210 includes a plunger 230 mounted for longitudinal sliding movement within the box shaped housing between a rearward retracted position (FIG. 14) and a forward advanced position (FIG. 15) (Page 15, lines 13-15). The plunger 230 has a recessed head 232 (best seen in FIG. 16) at a forward end thereof shaped for receiving the housing of a subcutaneous infusion set 214 (Page 15, lines 18-20). Centrally in the recess, the head 232 is provided with a projecting metal insertion needle 212 securely connected thereto (Page 15, lines 20-22). A drive spring 236 positioned behind wall 280 reacts between a rearward face 264 of the plunger head 232 (Page 15, lines 25-27). The drive spring 236 normally biases the plunger 230 toward the advanced position (Page 15, lines 27-28). The front end of the plunger 230 has a trigger button 258 cooperating with the wall 224 of the device housing 28 (Page 15, lines 28-29). In

the retracted state of the plunger shown in FIG. 14, the trigger button 258 extends through an opening 222 formed in the upper wall 224 of the device housing 228 and aligned for reception of a release tab 220 on the wall 219' (Page 15, lines 29-33).

The trigger button 258 may be adapted for fingertip depression to release the plunger 230 for spring-loaded travel toward the advanced position, and for corresponding transcutaneous placement of the insertion needle 212, and of the cannula 226 travelling therewith, through the patient's skin (Page 16, lines 1-4).

Before opening the device housing 210, the assembly is maintained under sterile conditions (Page 16, lines 10-12). A removable cover sheet 294 (FIG. 13) is sealed to wall 224 to cover opening 222 (Page 16, lines 12-13). All other walls defining the closed housing 210 being sealed together, the cover sheet 294, when being permeable allows the injector device 210 together with the infusion set 214 mounted on the insertion needle 212 to be sterilized in a conventional sterilization process using a gas, wherein the sterilizing agent flows through the permeable membrane of the sheet 294 (Page 16, lines 13-18).

FIGS. 17, 23a and 23b show an example of an infusion set 14 suitable for use with the injector device according to the invention. The infusion set 14 includes a housing 3 with an internal chamber (not shown) (Page 16, lines 21-22). The infusion set 14 has a protruding soft and flexible cannula 26, which communicates with the internal chamber (Page 16, lines 28-29).

FIG. 18 shows how priming of the infusion set may be carried out prior to the placement of the infusion set using an injector device with a plunger shown only in part and carrying a hollow insertion needle 12, 112 having a lateral opening 12B, 112B (Page 17, lines 1-4). The medical insertion needle 12, 112 of the injector device extends into the internal chamber 2 of the infusion set 14 and through the cannula 26, 126, when the infusion set 14 is mounted in position on the injector device (Page 17, lines 4-7).

FIGS. 19-21e show a presently preferred embodiment of the injector device assembly that includes an injector device 310 that includes respective removable covers 342, 394, the cover 342 having a hollow for accommodating a part of the insertion needle 312 when the cover 342 is secured to the housing 328 (Page 17, lines 13-19). A spring is used for advancing the plunger 330 to the advanced position (Page 17, lines 20-22). An insertion needle 312 is preferably secured in a stable manner to the plunger 330 of the injection device (Page 17, lines 25-26). The plunger 330 and the drive may conveniently be formed integrally as a single component in a molding process (Page 17, lines 28-30).

The housing 328 is flexible in the sense that the application of a manual force against diametrically opposed depressions 303 will give rise to a slight deformation of the housing 328 for bringing about a release of the plunger in the retracted position and cause a spring loaded movement of the plunger 330 towards the advanced position (Page 17, line 32-page 18, line 3). For maintaining the plunger 330 in the retracted

position the housing 328 is provided with two opposed ledges 366 (Page 18, lines 3-5). Moreover, the housing 328 is provided with opposed dovetail projections 301 extending along the same general direction as the insertion needle 312 and adapted to connect with complementary recesses in the aforementioned spring, to secure the spring in relation to the housing 328 (Page 18, lines 5-9).

The plunger 330 generally includes a head 332, a hub 331 and, opposite the head 332, an enlarged gripping portion 331' which allows a user to manually pull the plunger 330 to a retracted position (Page 18, lines 11-13). The head 332 has a recess 332' for accommodating the infusion set 326 with cannula 326 through which the insertion needle 312 extends (Page 18, lines 16-18).

The drive which acts to drive the plunger 330 from the retracted position towards the advanced position when the fingers 358 are disengaged includes a spring (Page 19, lines 6-8). The spring would normally allow the plunger to be retracted several times, and provide the required force for subsequently advancing the plunger 330 (Page 20, lines 23-25).

FIG. 24 shows a variation of the injector device assembly of FIGS. 19-21 wherein a glucose sensor is included.

2. <u>Summary of Independent Claims</u>

With the above summary in mind, claim 55 claims an embodiment of the invention as an injector device assembly, the assembly including an infusion set with a housing and a hollow cannula. An example of the infusion set is the infusion set 14 of

FIGS. 1-5 that includes a housing and a hollow cannula 26 (Page 7, lines 9-11 and 16-19). Another example of an infusion set is the infusion set 14 of FIGS. 17, 18, 23a and 23b, wherein the infusion set 14 includes a housing 3 and a soft and flexible cannula 26, which communicates with the internal chamber (Page 16, lines 21-22 and 28-29). Additional examples of the infusion set are the infusion sets 214, 314 shown in FIGS. 14-16 and 19 (Page 14, lines 28-30 and page 18, lines 18-20). The invention of claim 55 further recites a molded device housing. An example of the device housing is the device housing 28 of FIGS. 1-5 in which the housing can be molded (Page 7, lines 2-7). Additional examples of a molded device housing are the device housings 128, 228, 328 shown in FIGS. 6, 13 and 19. (Page 11, lines 23-26; page 14, line 33; page 17, line 32-page 18, line 3). The invention of claim 55 further recites a cover member removably secured to the device housing and covering an end of the device housing. Examples of the recited cover member are the cap 94 and the cover sheet 42 of FIGS. 1-5 (Page 11, lines 4-9). Additional examples of the cover member include the covers 142, 194, and 342, 394 shown in FIGS. 6 and 19 (Page 11, lines 26-28; page 17, lines 17-20). The invention of claim 55 also includes a molded plunger movably received within the device housing for movement between an advanced position and a retracted position. An example of the plunger is the plunger 30 of FIGS. 1-5 received within the device housing 28 and movable between an advanced position and retracted position (Page 7, lines 2-5). Additional examples of the plunger include the plungers 130, 230, 330 shown in FIGS. 6, 14 and 19. (Page 11, lines 23-26; page 15, lines13-15; page 17,

lines 28-30). The invention of claim 55 further recites a lock for releasably locking the plunger in the retracted position, the housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of the plunger. An example of the recited lock is shoulder 66 of FIG. 1 when engaged with trigger fingers 58 (Page 10, lines 5-7). Another example of a lock is shown in FIGS. 19 and 20d where the ledge 366 is releasably locked in engagement with finger 358. (Page 18, lines 24-27.) An example of the deformable device housing is device housing 28, 128, 328 that is pressed manually on opposed outside areas (Page 9, lines 4-7; page 13, line 32-page 14, line 2; page17, line 32-page 18, line 3). The invention of claim 55 also recites a drive for urging the plunger from the retracted position towards the advanced position. An example of the recited drive is drive spring 36, 136, 236 of FIGS. 1-2, 6-7 and 14-16 (Page 10, lines 7-11; page 12, lines 23-28; page 15, lines 25-28).

Claim 56 claims an embodiment of the invention as an injector device assembly, the assembly including an infusion set with a housing and a hollow cannula. An example of the infusion set is the infusion set 14 of FIGS. 1-5 that includes a housing and a hollow cannula 26 (Page 7, lines 9-11 and 16-19). Another example of an infusion set is the infusion set 14 of FIGS. 17, 18, 23a and 23b, wherein the infusion set 14 includes a housing 3 and a soft and flexible cannula 26, which communicates with the internal chamber (Page 16, lines 21-22 and 28-29). Additional examples of the infusion set are the infusion sets 214, 314 shown in FIGS. 14-16 and 19 (Page 14, lines

28-30 and page 18, lines 18-20). The invention of claim 56 further recites a molded device housing. An example of the device housing is the device housing 28 of FIGS. 1-5 in which the housing can be molded (Page 7, lines 2-7). Additional examples of a molded device housing are the device housings 128, 228, 328 shown in FIGS. 6, 13 and 19. (Page 11, lines 23-26; page 14, line 33; page 17, line 32-page 18, line 3). The invention of claim 56 further recites a cover member removably secured to the device housing and covering an end of the device housing. An example of the recited cover members are the cap 94 and the cover sheet 42 of FIGS. 1-5 (Page 11, lines 4-9). Additional examples of the cover member include the covers 142, 194, and 342, 394 shown in FIGS. 6 and 19 (Page 11, lines 26-28; page 17, lines 17-20). The invention of claim 56 also includes a molded plunger movably received within the device housing for movement between an advanced position and a retracted position. An example of the plunger is the plunger 30 of FIGS. 1-5 received within the device housing 28 and movable between an advanced position and retracted position (Page 7, lines 2-5). Additional examples of the plunger include the plungers 130, 230, 330 shown in FIGS. 6, 14 and 19. (Page 11, lines 23-26; page 15, lines13-15; page 17, lines 28-30). The invention of claim 56 further recites a lock for releasably locking the plunger in the retracted position, the housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of the plunger. An example of the recited lock is shoulder 66 of FIG. 1 when engaged with trigger fingers 58 (Page 10, lines 5-7). Another example of a lock is shown in FIGS. 19

and 20d where the ledge 366 is releasably locked in engagement with finger 358. (Page 18, lines 24-27.) An example of the deformable device housing is device housing 28, 128, 328 that is pressed manually on opposed outside areas (Page 9, lines 4-7; page 13, line 32-page 14, line 2; page17, line 32-page 18, line 3). The invention of claim 56 also recites a drive for urging the plunger from the retracted position towards the advanced position. An example of the recited drive is drive spring 36, 136, 236 of FIGS. 1-2, 6-7 and 14-16 (Page 10, lines 7-11; page 12, lines 23-28; page 15, lines 25-28). The invention of claim 56 includes a space for accommodating a tubing that forms part of the infusion set for delivery of medication to the hollow cannula. Examples of such a space include space 115 between the device housing 128 and the plunger 130 shown in FIG. 12 (Page 12, lines 3-7) and space 315 between the plunger 330 and the housing 328 shown in FIG. 20b (Page 20, lines 31-34).

Claim 58 claims an embodiment of the invention as an injector device assembly, the assembly including an infusion set with a housing and a hollow cannula. An example of the infusion set is the infusion set 114 of FIGS. 6-12 that includes a housing and a hollow cannula 126 (Page 11, line 33-page 12, line 7). The invention of claim 58 further recites a molded device housing. An example of the device housing is the device housing 128 of FIGS. 6-12 (Page 11, lines 23-24). The invention of claim 58 further recites a cover member removably secured to the device housing and covering an end of the device housing. An example of the recited cover member is the cover sheet 142 of FIGS. 6-12 (Page 14, lines 10-13). The invention of claim 58 also includes

a molded plunger movably received within the device housing for movement between an advanced position and a retracted position. An example of the plunger is the plunger 130 of FIGS. 6-12 received within the device housing 128 and movable between an advanced position and retracted position (Page 12, lines 13-16). The invention of claim 58 further recites a lock for releasably locking the plunger in the retracted position, the housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of the plunger. An example of the recited lock is shoulder 166 of FIG. 1 when engaged with trigger fingers 58 (Page 12, lines 17-21). An example of the deformable device housing is device housing 128 that is pressed manually on opposed outside areas (Page 13, line 32-page 14, line 2). The invention of claim 58 also recites a drive for urging the plunger from the retracted position towards the advanced position. An example of the recited drive is drive spring 136 of FIGS. 6, 7 and 12 (Page 12, lines 23-25). The invention of claim 58 includes indicia relating to the shelf life of the assembly on the cover member, and wherein the releasable cover member assures sterile conditions of the infusion set prior to releasing the cover member. An example of such a cover member with indicia is cover 142 (Page 14, lines 10-20).

Claim 61 claims an embodiment of the invention as an injector device assembly, the assembly including an infusion set with a housing and a hollow cannula. An example of the infusion set is the infusion set 14 of FIGS. 1-5 that includes a housing and a hollow cannula 26 (Page 7, lines 9-11 and 16-19). Another example of an

infusion set is the infusion set 14 of FIGS. 17, 18, 23a and 23b, wherein the infusion set 14 includes a housing 3 and a soft and flexible cannula 26, which communicates with the internal chamber (Page 16, lines 21-22 and 28-29). Additional examples of the infusion set are the infusion sets 214, 314 shown in FIGS. 14-16 and 19 (Page 14, lines 28-30 and page 18, lines 18-20). The invention of claim 61 further recites a molded device housing. An example of the device housing is the device housing 28 of FIGS. 1-5 in which the housing can be molded (Page 7, lines 2-7). Additional examples of a molded device housing are the device housings 128, 228, 328 shown in FIGS. 6, 13 and 19. (Page 11, lines 23-26; page 14, line 33; page 17, line 32-page 18, line 3). The invention of claim 61 further recites a cover member removably secured to the device housing and covering an end of the device housing. Examples of the recited cover member are the cap 94 and the cover sheet 42 of FIGS. 1-5 (Page 11, lines 4-9). Additional examples of the cover member include the covers 142, 194, and 342, 394 shown in FIGS. 6 and 19 (Page 11, lines 26-28; page 17, lines 17-20). The invention of claim 61 also includes a molded plunger movably received within the device housing for movement between an advanced position and a retracted position. An example of the plunger is the plunger 30 of FIGS. 1-5 received within the device housing 28 and movable between an advanced position and retracted position (Page 7, lines 2-5). Additional examples of the plunger include the plungers 130, 230, 330 shown in FIGS. 6, 14 and 19. (Page 11, lines 23-26; page 15, lines13-15; page 17, lines 28-30). The invention of claim 61 further recites a lock for releasably locking the plunger in the

retracted position, the housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of the plunger. An example of the recited lock is shoulder 66 of FIG. 1 when engaged with trigger fingers 58 (Page 10, lines 5-7). Another example of a lock is shown in FIGS. 19 and 20d where the ledge 366 is releasably locked in engagement with finger 358 (Page 18, lines 24-27.) An example of the deformable device housing is device housing 28, 128, 328 that is pressed manually on opposed outside areas (Page 9, lines 4-7; page 13, line 32-page 14, line 2; page17, line 32-page 18, line 3). The invention of claim 61 also recites a drive for urging the plunger from the retracted position towards the advanced position. An example of the recited drive is drive spring 36, 136, 236 of FIGS. 1-2, 6-7 and 14-16 (Page 10, lines 7-11; page 12, lines 23-28; page 15, lines 25-28). The invention of claim 61 includes having the plunger include an insertion needle secured thereto by a stable connection preventing loss of the insertion needle during use of the injector device, the insertion needle extending through the cannula with the cannula oriented for transcutaneous placement upon movement of the plunger from the retracted position to the advanced position, the insertion needle secured to the plunger being removable from the cannula while maintaining the transcutaneous placement of the cannula. An example of the recited insertion needle is insertion needle 12 of FIGS. 1-5 which passes through cannula 26 (Page 7, lines 19-22) and can be removed from the cannula 26 after placement of transcutaneous placement of cannula 26 (Page 7,

lines 22-25). Additional examples of the needle include insertion needle 112, 212, 312 shown in FIGS. 11, 16 and 19.

Claim 66 claims an embodiment of the invention as an injector device assembly, the assembly including an infusion set including at least a housing and a hollow cannula. An example of the infusion set is the infusion set 14 of FIGS. 1-5 that includes a housing and a hollow cannula 26 (Page 7, lines 9-11 and 16-19). Another example of an infusion set is the infusion set 14 of FIGS. 17, 18, 23a and 23b, wherein the infusion set 14 includes a housing 3 and a soft and flexible cannula 26, which communicates with the internal chamber (Page 16, lines 21-22 and 28-29). Additional examples of the infusion set are the infusion sets 214, 314 shown in FIGS. 14-16 and 19 (Page 14, lines 28-30 and page 18, lines 18-20). The invention of claim 66 further recites a molded device housing that receives at least a part of the infusion set, the part positioned removably from and within the device housing. An example of the molded device housing that contains the insertion set is the device housing 28 of FIGS. 1-5 in which the insertion set is removably positioned therein (Page 7, lines 2-7 and 22-25, Page 10, lines 31-34). Additional examples of a molded device housing are the device housings 128, 228, 328 shown in FIGS. 6, 13 and 19 (Page 11, lines 23-26; page 14, line 33; page 17, line 32-page 18, line 3). The invention of claim 66 also includes a molded plunger movably received within the device housing for transcutaneous placement of the hollow cannula by movement of the plunger between an advanced position and a retracted position. An example of the plunger is the plunger 30 of FIGS. 1-5 received

within the device housing 28 and movable between an advanced position and a retracted position (Page 7, lines 2-5). Additional examples of the plunger include the plungers 130, 230, 330 shown in FIGS. 6, 14 and 19. (Page 11, lines 23-26; page 15, lines 13-15; page 17, lines 28-30). The invention of claim 66 further recites a lock for releasably locking the plunger in the retracted position. An example of the recited lock is shoulder 66 of FIG. 1 when engaged with trigger fingers 58 (Page 10, lines 5-7). Another example of a lock is shown in FIGS. 19 and 20d where the ledge 366 is releasably locked in engagement with finger 358 (Page 18, lines 24-27.) The invention of claim 66 also recites a drive including a spring for urging the plunger from the retracted position towards the advanced position. An example of the recited drive is drive spring 36, 136, 236 of FIGS. 1-2, 6-7 and 14-16 (Page 10, lines 7-11; page 12, lines 23-28; page 15, lines 25-28). The invention of claim 66 further recites a cover removably connected to a front end portion of the housing and covering an opening defined at the front end portion of the housing, the cover receiving a part of the infusion set. Examples of the recited cover are the cap 94 and the cover sheet 42 of FIGS. 1-5 (Page 11, lines 4-9). Additional examples of the cover member include the covers 142, 194, and 342, 394 shown in FIGS. 6 and 19 (Page 11, lines 26-28; page 17, lines 17-20).

Regarding only independent claims 55, 56, 58, 61 and 66 and dependent claims 60, 62, 63, 70 and 73, which are argued separately below in Section VII, there are no means-plus-function terms or step-plus-function terms present therein. This statement

is not to be construed as an admission whether or not the remaining claims contain means-plus-function terms or step-plus-function terms.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There are three grounds of rejection presented for review:

1) the rejection of claims 55, 57, 60, 66 and 70-73 under 35 U.S.C. § 102(b) as being anticipated by Miskinyar, U.S. Patent No. 4,894,054;

2) the rejection of claims 55-57, 60-64, 66 and 69-73 under 35 U.S.C. § 102(e) as being anticipated by Safabash et al., U.S. Patent No. 6,293,925; and

3) the rejection of claims 58 and 59 under 35 U.S.C. § 103 as being obvious in view of Miskinyar and Teeple, Jr., U.S. Patent No. 5,807,316.

VII. ARGUMENT

A. 35 U.S.C. § 102

1. Miskinyar

a. Independent Claim 55 and Dependent Claims

i. Claims 55 and 57

Claims 55 and 57 were rejected in the Office Action of April 22, 2009 (hereinafter "the Office Action") under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. In particular, independent claim 55 recites "an infusion set with a housing and a hollow cannula." The Examiner at page 2 of the Office Action has asserted that Miskinyar discloses an infusion set with a housing

corresponding to item 10 and a cannula corresponding to item 22. It is noted that the Examiner has taken the position at page 4 of the Office Action that the term "infusion set" has been given no special definition in the specification and so could mean a needle, "a pump, an IV bag, essentially anything with a fluid conduit for subcutaneous fluid delivery." Appellants traverse such an interpretation on several fronts. First, an "infusion set," according to Appellants' specification, is used to infuse medical fluids such as insulin to a patient and generally includes a housing with an internal chamber (not shown) that receives medication via infusion tubing (Page 7, lines 9-11). The infusion set is mounted on the injector device for transcutaneous insertion of the cannula. After transcutaneous placement of the cannula, the injector device is retracted from the infusion set that is left on the skin for delivery of medication therethough (Page 7, lines 22-25). Based on Appellants' specification,one of ordinary skill would not interpret an infusion set in the same manner as the Examiner. The Examiner's interpretation is improper for the additional reason that the Examiner ignores the language of the claims. For example, claim 55 specifically recites that the infusion set includes "a housing and a hollow cannula." A pump, an IV bag, and many items with a fluid conduit for subcutaneous fluid delivery do not include a cannula. In addition, hypodermic needle 22 alone does not anticipate the infusion set of claim 55 since the infusion set requires both a housing and a cannula. Accordingly, the Examiner's interpretation of "infusion set" has no merit.

Based on the proper interpretation of "infusion set," Miskinyar does not disclose using an infusion set. The Examiner has incorrectly relied on Miskinyar, aptly titled a "Preloaded Automatic Disposable Syringe," i.e., an innoculator. The syringe in Miskinyar is preloaded with a precisely measured dosage of medication for the patient (Col. 3, line 67 - Col. 4, line 2).

The rejection is improper for the additional reason that Miskinyar does not disclose a "device housing manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger." The Examiner at pages 4-5 of the Office Action has asserted that button 33 is part of housing 10. Assuming for argument's sake only that button 33 can be considered part of housing 10, the fact remains that Miskinyar does not disclose that button 33 is deformable. A review of Appellants' specification regarding the embodiment of FIGS. 1-5 reveals that:

> [R]elease of the plunger 30 may be caused by pressing manually on diametrically opposed outside areas of the device housing 28 to deform the housing 28 and thereby effect release of the trigger arms 38. (P. 9, ll. 5-7).

A similar statement is made at page 13, line 32 to page 14, line 2 regarding the embodiment of FIGS. 6-12. In each embodiment, a user presses against the housing 28, 128 so that the shape of the housing changes to such an extent that the housing contacts the trigger arms 38, 138 resulting in the release of the plunger 30, 130. Thus, "deform," as understood by one of ordinary skill reviewing Appellants' specification, means that the shape of an object will be changed. This meaning is in agreement with

the definition of "deform" which is "to alter the shape of by stress" according to Webster's Ninth New Collegiate Dictionary. With the above meaning of "deform" in mind, Miskinyar does not disclose deforming button 33. While Miskinyar does disclose changing the position of button 33, Miskinyar does not disclose altering the shape/deforming button 33. Accordingly, Miskinyar does not anticipate claim 55 and so the rejection should be reversed.

Claim 57 depends directly on claim 55 and so its rejection should be reversed for the reasons given above with respect to claim 55.

ii. Claim 60

Claim 60 was rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. In particular, claim 60 depends directly on claim 55 and so is not anticipated for the reasons given above at pages 24-27 in Section VII.A.1.a.i. with respect to claim 55. The claim is not anticipated for the additional reason that Miskinyar does not disclose "a removable cover covering said infusion set includes a hollow portion for receiving a part of an insertion needle when said plunger is in said advanced position." The Examiner at page 4 of the Office Action has asserted that the tape 72 of Miskinyar anticipates the recited removable cover. However, this conclusion does not take proper account of the claim requirement that the cover must be removably connected to the housing. Miskinyar's "tape 72" cannot be considered a removable housing cover of the claimed invention. Miskinyar actually teaches away from the claimed removable

housing cover: "tape 72 which is permanently bonded to the housing." (Col. 4, line 2, emphasis added). In addition, the permanently bonded tape 72 does not permit any removably positioned device behind the tape 72 to be removable from the plunger. In addition, tape 72 does not include a hollow for receiving a part of the insertion needle. The Examiner at pages 2 and 4 of the Office Action asserts that the aperture 60 in tape 72 formed when needle 22 pierces tape 72 is a hollow. Such an interpretation of hollow fails to take into account that claim 60 requires that the removable cover covers the infusion set. When the hole is formed, the tape 72 does not cover ampoule 74. Since tape 72 with a hole does not cover ampoule 74, claim 60 is not anticipated by Miskinyar and so the rejection is improper and should be reversed.

iii. Claim 73

Claim 73 was rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. In particular, claim 73 depends directly on claim 55 and so is not anticipated for the reasons given above at pages 24-27 in Section VII.A.1.a.i. with respect to claim 55. The claim is not anticipated for the additional reason that Miskinyar does not disclose a pair of manual engagement areas that are pressed radially inwardly in said second geometrical configuration. As mentioned previously in Section VII.A.1.a.i., button 33 of Miskinyar is not deformable and so it follows that Miskinyar does not disclose the recited pair of manual engagement areas. Without such disclosure, claim 73 is not anticipated by Miskinyar and so the rejection is improper and should be reversed.

b. Independent Claim 66 and Dependent Claims

i. Claims 66 and 72

Claims 66 and 72 were rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. In particular, independent claim 66 recites "an infusion set including at least a housing and a hollow cannula" and "said infusion set positioned removably from and within said device housing." For reasons similar to those given above in Section VII.A.1.a.i. with respect to the infusion set recited in claim 55, Miskinyar does not disclose the infusion set recited in claim 66 and so the rejection is improper and should be reversed.

Assuming for argument's sake only that needle 22 is an infusion set as proposed by the Examiner at page 4 of the Office Action, then the rejection is improper because Miskinyar does not disclose that a part of an infusion set received by device housing is "positioned removably from and within said device housing." Indeed, the Examiner at page 3 of the Office Action fails to recite one portion of Miskinyar that discloses having ampoule 74 and hypodermic needle 22 being separable from ampoule member 18. Miskinyar discloses that hypodermic needle 22 is attached to ampoule member 18 since it moves with ampoule member 18 from the loaded position shown in FIG. 2 to the released position of FIG. 3. Neither needle 22 nor ampoule 74 is removable. For example, if it is the Examiner's position that needle 22 was intended to be cut from the

housing and so was separable in the manner recited in claim 66[2], then Miskinyar does not disclose that its needle is intended to be cut from the member 18. Does cutting off a needle and leaving the needle in a patient's skin while the remainder of the device is removed sound like a good idea? Obviously not. While in general it might be acceptable practice in the medical field to use a needle to penetrate epidermis to inoculate a patient, inserting a needle, cutting it off, and leaving it in the patient would not be safe, sanitary, or intended.

As mentioned above, claim 66's infusion set includes a housing. The Examiner at page 3 of the Office Action has asserted that ampoule 74 is a housing of an insertion set. Assuming for argument's sake only that ampoule 74 is a housing, it is not separable from ampoule member 18. Indeed, ampoule 74 is sealed to (i.e., not removable or releasable from) the inner walls of the ampoule chamber 24:

> Thus the needle 22 is extended before air pressure is applied to the ampoule 74 contained within the ampoule chamber 24. The ampoule 74 is formed by an elastic balloon which is received within and sealed to the inner walls of the ampoule chamber, containing medication 78 within its sealed interior. (Miskinyar Col. 3, lines 47-53, emphasis supplied).

Since both hypodermic needle 22 and ampoule 74 are not separable from ampoule member 18, Miskinyar does not disclose an infusion set that is separable from

[2] The proposed cutting of a needle to show a removable infusion set was proposed by Examiner Moulton (previously MacNeill) in an Advisory Action mailed on August 14, 2008 regarding the present application.

a plunger as recited in claim 66. Accordingly, the rejection is improper and should be reversed.

The rejection is improper for the additional reason that Miskinyar does not disclose "a cover removably connected to a front end portion of said housing and covering an opening defined in the front end portion of said housing, said cover receiving a part of said infusion set." At page 4 of the Office Action, the Examiner asserts that the tape 72 receives needle 22 when the needle pierces through it. Such an assertion fails to take into account that claim 66 requires that the removable cover covers an opening defined by a front end portion of a housing. When the aperture 60 is formed, the tape 72 does not cover the opening of the housing. Since tape 72 with an aperture 60 does not cover the opening of the housing, claim 66 is not anticipated by Miskinyar and so the rejection is improper and should be reversed. In addition, claim 66 is not anticipated for the reasons given above at pages 27-28 in Section VII.A.1.a.ii with respect to the removable cover. Miskinyar discloses a tape 72 which is permanently bonded to the housing.

Claim 72 depends directly on claim 66 and so its rejection should be reversed for the reasons given above with respect to claim 66.

ii. Claims 70 and 71

Claim 70 was rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. In particular, claim 70

depends directly on claim 66 and so is not anticipated for the reasons given above at pages 28-31 in Section VII.A.1.b.i. with respect to claim 66. The claim is not anticipated for the additional reason that Miskinyar does not disclose having a device housing that "is manually deformable to effect release of said plunger." The Examiner at pages 4 and 5 of the Office Action has asserted that button 33 is part of housing 10. As pointed out in Section VII.A.1.a.i. with respect to claim 55, button 33 is not deformable. Accordingly, claim 70 is not anticipated by Miskinyar and so the rejection is improper and should be withdrawn.

Claim 71 depends directly on claim 70 and so its rejection should be reversed for the reasons given above with respect to claim 70.

2. Safabash et al.

a. Independent Claims 55, 56 and 61 and Dependent Claims

i. Claims 55-57 and 61-64

Claims 55-57 and 61-64 were rejected in the Office Action under 35 U.S.C. § 102(e) as being anticipated by Safabash et al. Appellants traverse the rejection. In particular, independent claims 55, 56 and 61 recite a "device housing manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger." The Examiner at page 3 of the Office Action has asserted that release button 508 is deformable. Assuming for argument's sake only that the button 508 can be considered part of barrel 502, the fact remains that Safabash et al. does not disclose that button 508 is deformable. As

pointed out above in Section VII.A.1.a.i., Appellants' specification defines deformation to mean that the shape of an object will be changed. With the above meaning of "deform" in mind, Safabash et al. does not disclose deforming button 508. While Safabash et al. does disclose changing the position of button 508, Safabash et al. does not disclose altering the shape/deforming button 508.

In addition, claims 55, 56 and 61 recite a removable cover member having "said cover member covering an end of said device housing," According to the Examiner, the cover of Safabash et al. consists of adhesive backing 416 and needle guard 414. However, Safabash et al. shows both the adhesive backing 416 and the needle guard 414 are seated inside the barrel 502. Safabash et al. is silent, however, as to how the needle guard 414 and the adhesive backing are removably connected to the device housing as recited in independent claims 55, 56 and 61. Indeed, the teachings in Safabash et al. undermine the very reason being proffered by the Examiner as to why the adhesive backing 416 and the needle guard 414 do not removably connect to the device housing. As taught by Safabash et al., a "user presses against the piercing member guard 414 (or needle guard) to seat the piercing member hub (or needle hub) and the insertion set 400 *in the cavity* of the carrier body 504." (Safabash, et al. Col. 19, lines 27–30 (emphasis added); see also FIGS. 40a–40d.) Therefore, the needle guard 414 and the adhesive backing 416 are prevented from covering the "barrel 502 (or device housing) having a surface seat 501." (Safabash et al., Col. 15, line 67 through Col. 16, line 1.)

Accordingly, Safabash et al. does not anticipate claims 55, 56 and 61 and so their rejections should be reversed.

Claim 57 depends directly on claim 55 and so its rejection should be reversed for the reasons given above with respect to claim 55. Similarly, claim 64 depends directly on claim 61 and so its rejection should be reversed for the reasons given above with respect to claim 61.

ii. Claim 60

Claim 60 was rejected in the Office Action under 35 U.S.C. § 102(e) as being anticipated by Safabash et al. Appellants traverse the rejection. In particular, claim 60 depends directly on claim 55 and so is not anticipated for the reasons given above at pages 32-34 in Section VII.A.2.a.i. with respect to claim 55. The claim is not anticipated for the additional reason that Safabash et al. does not disclose "a removable cover covering said infusion set includes a hollow portion for receiving a part of an insertion needle when said plunger is in said advanced position." The Examiner at page 3 of the Office Action has asserted that the piercing member guard 414 and the adhesive backing 416 correspond to the recited cover member. Such reliance is incorrect. Adhesive backing 416 lacks a hollow portion. Regarding piercing member guard 414 it is placed over piercing member 402 to move the carrier body 504 to a retracted position as shown in FIG. 40c (Col. 19, lines 35-42). As shown in FIG. 40d, the guard 414 is later removed. It follows that guard 414 does not cover an end of a device housing as recited in claim 55. Instead, guard 414 covers a piercing member 402. Accordingly,

Safabash et al. does not disclose the recited cover member and so the rejection is improper and should be reversed.

iii. Claim 62

Claim 62 was rejected in the Office Action under 35 U.S.C. § 102(e) as being anticipated by Safabash et al. Appellants traverse the rejection. In particular, claim 62 depends directly on claim 61 and so is not anticipated for the reasons given above at pages 32-34 in Section VII.A.2.a.i. with respect to claim 61. The claim is not anticipated for the additional reason that Safabash et al. does not disclose an "insertion needle being in frictional engagement with said infusion set." It is noted that the Examiner has failed to identify where Safabash et al. discloses such a frictional engagement. Accordingly, Safabash et al. does not disclose the recited frictional engagement and so the rejection is improper and should be reversed.

iv. Claim 63

Claim 63 was rejected in the Office Action under 35 U.S.C. § 102(e) as being anticipated by Safabash et al. Appellants traverse the rejection. In particular, claim 63 depends directly on claim 61 and so is not anticipated for the reasons given above at pages 32-34 in Section VII.A.2.a.i. with respect to claim 61. The claim is not anticipated for the additional reason that Safabash et al. does not disclose an "insertion needle is secured to said plunger by press-fit." It is noted that the Examiner has failed to identify where Safabash et al. discloses such a press-fit. Accordingly, Safabash et al. does not disclose the recited press-fit and so the rejection is improper and should be reversed.

v. Claim 73

Claim 73 was rejected in the Office Action under 35 U.S.C. § 102(e) as being anticipated by Safabash et al. Appellants traverse the rejection. In particular, claim 73 depends directly on claim 55 and so is not anticipated for the reasons given above at pages 32-34 in Section VII.A.2.a.i. with respect to claim 55. The claim is not anticipated for the additional reason that Safabash et al. does not disclose a pair of manual engagement areas that are pressed radially inwardly in said second geometrical configuration. As mentioned previously in Section VII.A.2.a.i., button 508 of Safabash et al. is not deformable and so it follows that Safabash et al. does not disclose the recited pair of manual engagement areas. Without such disclosure, claim 73 is not anticipated by Safabash et al. and so the rejection is improper and should be reversed.

b. Independent Claim 66 and Dependent Claims

i. Claim 66, 69 and 72

Claims 66, 69 and 72 were rejected in the Office Action under 35 U.S.C. § 102(e) as being anticipated by Safabash et al. Appellants traverse the rejection. In particular, independent claim 66 recites "a cover removably connected to a front end portion of said housing and covering an opening defined in the front end portion of said housing, said cover receiving a part of said infusion set." At page 3 of the Office Action, the Examiner asserts that the piercing member guard 414 and adhesive backing 416 corresponds to the recited cover.

However, Safabash et al. shows both the adhesive backing 416 and the needle guard 414 are seated inside the barrel 502 and do not removably connect to a front end

portion of the housing. Safabash et al. is silent, however, as to how the needle guard 414 and the adhesive backing are removably connected to the device housing as recited in independent claims 55, 56 and 61. Indeed, the teachings in Safabash et al. undermine the very reason being proffered by the Examiner as to why the adhesive backing 416 and the needle guard 414 do not removably connect to the device housing. As taught by Safabash et al., a "user presses against the piercing member guard 414 (or needle guard) to seat the piercing member hub (or needle hub) and the insertion set 400 *in the cavity* of the carrier body 504." (Safabash, et al. Col. 19, lines 27–30 (emphasis added); see also Figs 40a–40d.) Therefore, the needle guard 414 and the adhesive backing 416 are prevented from covering the "barrel 502 (or device housing) having a surface seat 501." (Safabash et al., Col. 15, line 67 through Col. 16, line 1.) Accordingly, Safabash et al. does not anticipate claim 66 and so the rejection should be reversed.

Claims 69 and 72 depend directly on claim 66 and so their rejections should be reversed for the reasons given above with respect to claim 66.

ii. Claims 70 and 71

Claim 70 was rejected in the Office Action under 35 U.S.C. § 102(e) as being anticipated by Safabash et al. Appellants traverse the rejection. In particular, claim 70 depends directly on claim 66 and so is not anticipated for the reasons given above at pages 36-37 in Section VII.A.1.b. with respect to claim 66. The claim is not anticipated for the additional reason that Safabash et al. does not disclose having a device housing

that "is manually deformable to effect release of said plunger." The Examiner at page 3 of the Ofice Action has asserted that button 508 is part of the barrel 502. As pointed out in Section VII.A.2.a.i. with respect to claim 55, button 508 is not deformable. Accordingly, claim 70 is not anticipated by Safabash et al. and so the rejection is improper and should be withdrawn.

Claim 71 depends directly on claim 70 and so its rejection should be reversed for the reasons given above with respect to claim 70.

B. 35 U.S.C. § 103

Claims 58 and 59 were rejected in the Office Action under 35 U.S.C. § 103 as being obvious in view of Miskinyar and Teeple, Jr. Appellants traverse the rejection. In particular, independent claim 58 recites "device housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration." As mentioned above in Section VII.A.1.a.i., Miskinyar fails to disclose a deformable housing. Teeple, Jr. is directed to the mixing and delivery of anesthesia and not to an injector device assembly. Teeple, Jr. clearly fails to make up the deficiencies of Miskinyar.

The rejection is improper for the additional reason that both Miskinyar and Teeple, Jr. do not disclose the recited indicia. The Examiner admits Miskinyar does not teach the "indicia" but, with a broad brush, suggests that Teeple, Jr. provides the missing element. However, the Examiner is taking Teeple, Jr. out of context. That

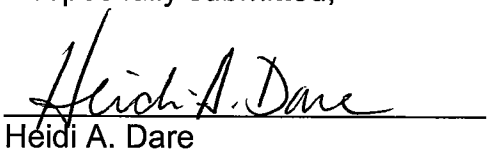
reference is related to shelf life of anesthetic drugs that break down over time when stored in vials. See Teeple, Jr., col. 18, ll. 19–28. Also, the Examiner's truncated reading of the claim limitation reads out of the claim the recited indicia on the "cover member, and wherein the releasable cover member assures sterile conditions of the infusion set prior to releasing the cover member." The Examiner does not explain how the bar codes for tracking expired anesthetic drugs would assure "sterile conditions of the infusion set prior to releasing the cover member." This is not taught, described, or even remotely suggested by Teeple, Jr.

Claim 59 depends directly on claim 58 and so its rejection should be reversed for the reasons given above with respect to claim 58.

For the reasons given above, Appellants respectfully submit that the rejections should be reversed and the claims should be allowed.

Respectfully submitted,

Dated: August 5, 2009



Heidi A. Dare
Registration No. 50,775
Attorney for Appellants

BRINKS HOFER
GILSON & LIONE
P.O. Box 10395
Chicago, Illinois 60610
(312) 321-4200

VIII. CLAIMS APPENDIX

55. An injector device assembly, comprising:

an infusion set including a housing and a hollow cannula,

a molded device housing,

a cover member removably secured to said device housing, said cover member covering an end of said device housing,

a molded plunger movably received within said device housing for movement between an advanced position and a retracted position,

a lock for releasably locking said plunger in said retracted position, said device housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger, and

a drive for urging said plunger from the retracted position towards said advanced position.

56. An injector device assembly, comprising:

an infusion set including a housing and a hollow cannula;

a molded device housing;

a cover member removably secured to said device housing, said cover member covering an end of said device housing;

a molded plunger movably received within said device housing for movement between an advanced position and a retracted position;

a lock for releasably locking said plunger in said retracted position, said device housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger; and

a drive for urging said plunger from the retracted position towards said advanced position;

wherein said device housing includes a space for accommodating a tubing that forms part of said infusion set for delivery of medication to said hollow cannula.

57. The injector device assembly of claim 55, wherein the device housing has a forward end defining a generally planar surface for placement against the skin of a patient with the device housing in a predetermined orientation relative to the patient's skin.

58. An injector device assembly, comprising:

an infusion set including a housing and a hollow cannula;

a molded device housing;

a cover member removably secured to said device housing, said cover member covering an end of said device housing;

a molded plunger movably received within said device housing for movement between an advanced position and a retracted position;

a lock for releasably locking said plunger in said retracted position, said device housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger;

a drive for urging said plunger from the retracted position towards said advanced position; and

indicia relating to the shelf life of said assembly on said cover member, and wherein the releasable cover member assures sterile conditions of the infusion set prior to releasing the cover member.

59. The injector device assembly of claim 58, said plunger being in said advanced position prior to first time removal of said at least one cover member.

60. The injector device assembly of claim 55, wherein a removable cover covering said infusion set includes a hollow portion for receiving a part of an insertion needle when said plunger is in said advanced position.

61. An injector device assembly, comprising:

an infusion set including a housing and a hollow cannula;

a molded device housing;

a cover member removably secured to said device housing, said cover member covering an end of said device housing;

a molded plunger movably received within said device housing for movement between an advanced position and a retracted position;

a lock for releasably locking said plunger in said retracted position, said device housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger; and

a drive for urging said plunger from the retracted position towards said advanced position, said plunger having an insertion needle secured thereto by a stable connection preventing loss of said insertion needle during use of said injector device, said insertion needle extending through said cannula with the cannula oriented for transcutaneous placement upon movement of the plunger from the retracted position to the advanced position, said insertion needle secured to said plunger being removable from said cannula while maintaining the transcutaneous placement of the cannula.

62. The injector device assembly of claim 61, said insertion needle being in frictional engagement with said infusion set.

63. The injector device assembly of claim 61, wherein the insertion needle is secured to said plunger by press-fit.

64. The injector device assembly of claim 61, wherein the insertion needle is hollow and has an entry port and an exit port.

66. An injector device assembly comprising:

an infusion set including at least a housing and a hollow cannula,

a molded device housing receiving at least a part of said infusion set, said part of said infusion set positioned removably from and within said device housing;

a molded plunger movably received within said device housing for transcutaneous placement of said hollow cannula by movement of said plunger between an advanced position and a retracted position,

a lock for releasably locking said plunger in said retracted position,

a drive including a spring for urging the plunger from the retracted position towards the advanced position,

a cover removably connected to a front end portion of said housing and covering an opening defined in the front end portion of said housing,

said cover receiving a part of said infusion set.

69. The injector device assembly of claim 66, further comprising a medical insertion needle substantially non-detachably attached to said plunger, said medical insertion needle extending through said cannula.

70. The injector device assembly of claim 66, wherein said device housing is manually deformable to effect release of said plunger.

71. The injector device assembly of claim 70, wherein said molded device housing comprises manual engagement areas.

72. The injector device assembly of claim 66, wherein said cover comprises a hollow portion.

73. The injector device assembly of claim 55, wherein said housing comprises a pair of manual engagement areas, said manual engagement areas being pressed radially inwardly in said second geometrical configuration.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.